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09/463,276	05/12/2000	Neal L. First	96429/9085	6126

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EXAMINER

WOITACH, JOSEPH T

ART UNIT	PAPER NUMBER
1632	11

DATE MAILED: 05/09/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/463,276	FIRST ET AL.	
	Examiner	Art Unit	
	Joseph Woitach	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

**A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM
 THE MAILING DATE OF THIS COMMUNICATION.**

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 14 February 2002.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-15 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-15 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s). _____.
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152)
 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. 6) Other: _____

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File

DETAILED ACTION

This application filed May 12, 2000, is a 371 national stage filing of PCT/US98/15387, filed July 24, 1998.

Applicants' amendment filed February 14, 2002, paper number 10, has been received and entered. Claims 1, 5, 6, 8 and 12-15 have been amended. Claims 1-15 are pending and currently under examination.

Oath/Declaration

The objection to the declaration is withdrawn. The new declaration filed February 4, 2002, paper number 9, is in compliance with 37 CFR 1.67(a).

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 12, 14 and 15 rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter is withdrawn.

Claim amendments to recite a 'non-human embryo' have obviated the basis of the rejection.

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Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 15 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. 37 CFR 1.118 (a) states that "No amendment shall introduce new matter into the disclosure of an application after the filing date of the application". In the instant case the limitation encompassed by the recitation of the species 'is a mammalian species' in claims 1 and 15 is considered new matter. The specification teaches that invention is drawn to generating chimeric embryos through nuclear transfer methodology wherein a nucleus of one species is combined with an enucleated oocyte from a different species. In the introduction, a review of the art teaches that nuclear transfer has been accomplished for many species ranging from amphibians to primates (page 1; lines 16-26). In the description of the invention, the applicability of the instantly claimed invention for cloning is described in the context of results obtained for amphibians to sheep. A 'recipient oocyte' is defined as encompassing any mature oocyte which is at the correct stage of development to be fertilized and serves as a recipient for the donor cell nucleus (page 9; lines 2-10). The specification specifically teaches that the recipient oocyte is from 'any species' (page 9; lines 21-22). It is noted that a

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preferred embodiment is directed to using specifically bovine oocytes, however other species are discussed in the disclosure and art of record. Additionally, the specification does not teach or suggest that the specific methods and examples provided for the preferred embodiment of a bovine oocyte were exemplary of a range encompassing all mammals in general or excludes other species of animals. Though mammals are encompassed in the broad range of all possible species, the specification does not teach or support the specific range of only mammals. Further, though the preferred embodiment of a bovine is a mammal, the specification fails to support that a single preferred species is exemplary of the broad range of any and all mammals, or conversely in light of the teaching that an oocyte from any species can be used, the specification fails to support that exclusion of all species besides mammals was ever specifically contemplated.

MPEP 2163.06 notes “If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. *In re Rasmussen*, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981).” MPEP 2163.02 teaches that “Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application. MPEP 2163.06 further notes “When an amendment is filed in reply to an objection or rejection based on 35 U.S.C. 112, first paragraph, a study of the entire application is often necessary to

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determine whether or not “new matter” is involved. *Applicant should therefore specifically point out the support for any amendments made to the disclosure*” (emphasis added).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5, 6 and 8 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn.

Claim amendments have obviated the basis of the specific rejections.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 12 and 15 stand rejected under 35 U.S.C. 102(b) as being anticipated by Barnes *et al.* (Molecular Reproduction and Development, 1992 IDS reference) as evidenced by Telford *et al.* (Mol. Reprod. Dev. 26:90-100, 1990).

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Applicants summarize the instantly claimed invention noting claim amendments and that claim 15 is drawn to a composition comprising certain characteristics, and is not limited to an embryo made by the methods of claim 1 or 13. Specifically, Applicants argue that the bovine embryo disclosed by Barnes *et al.* does anticipate the instantly claimed embryo. See Applicants' amendment, top of page 5. Applicants' arguments have been fully considered and are found persuasive in part.

Examiner agrees that because claim 13 has been amended to recite that the nuclear material (the donor cell) is not from a bovine, a bovine embryo would not anticipate the embryo of claim 14, therefore the rejection is withdrawn over claim 14.

With respect to claim 15, it is noted that though claim 15 recites two species, there is no limitation in the claim that the first and second species are different or that the resulting embryo is chimeric or possesses any characteristics of a chimeric embryo. The instant specification discloses nuclear transfer between animals of the same species, therefore, claim 15 can reasonably be interpreted to include nuclear transfer between two animals of the same species. Because the resulting embryo comprising the nuclear material from one bovine and the oocyte of a second bovine would be indistinguishable from the bovine embryo taught in Barnes *et al.*, the embryo of claim 15 is anticipated.

With respect to claim 12, it is noted that the method of claim 1 has been amended to recite that the two species are not the same, and therefore the resulting embryo that upon fusion the cell will initially comprise both nuclear material and an oocyte/cytoplasm from two different

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species. An embryo is not specifically defined in the specification, however the art defines the embryo as the developing organism from conception until approximately organogenesis and development of the fetus (see Stedmans dictionary, page 559). The specification supports this definition in light of its production and analysis of the viability of chimeric embryos (pages 23-25). Examiner would concede that at the time of fusion the single cell embryo may be distinguishable from an embryo derived through IVF, however the claims are not limited to a single cell embryo. During embryogenesis initially the maternal mRNA and proteins regulate the earliest stages of development, however as the embryo develops the maternal molecules decay and the process becomes dependent on expression of genetic information, *i.e.* the nuclear donor (see Introduction section of Telford *et al.*). Therefore, because development of the embryo ultimately becomes controlled by the nuclear donor, an embryo at later stages of development would be indistinguishable from that derived other means. In the instant case, if one were to use the nucleus of a bovine and the oocyte of any other species, subsequent development of the resulting embryo would reflect the properties conferred upon it by the genomic information. Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. Whether the rejection is based on "inherency" under 35 USC 102, on "*prima facie* obviousness" under 35 USC 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and

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compare prior art products. *In re Best, Bolton, and Shaw*, 195 USPQ 430, 433 (CCPA 1977) citing *In re Brown*, 59 CCPA 1036, 459 F.2d 531, 173 USPQ 685 (1972). The instant specification describes *in vitro* and *in vivo* methods of culturing an embryo generated by nuclear transfer. Barnes *et al.* describe the development of a bovine embryo. In view of the breadth of what an ‘embryo’ encompasses, a bovine embryo at a later stage of development and an embryo first generated by nuclear transfer wherein the nuclear material of a bovine at a later stage of development would be indistinguishable.

Accordingly, Barnes *et al.* anticipate claims 12 and 15, and therefore, the rejection is maintained.

Claims 12, 14 and 15 stand rejected under 35 U.S.C. 102(b) as being anticipated by Gurdon (J. Cell. Sci., 1986 IDS reference).

Applicants summarize the teaching of Gurdon and note that the recipient oocyte in Gurdon was from an amphibian. Applicants note the amendments to the claims to recite a mammalian recipient oocyte have been made to further clarify the invention and that they overcome the rejection. See Applicants’ amendment, pages 5-6. Applicants’ arguments have been fully considered but not found persuasive.

Examiner would agree that the embryos specifically disclosed in figure 6 encompass only the use of amphibian oocyte, however Gurdon discuss the nuclear transfer in groups other than amphibian. In particular, Gurdon summarizes the early success of nuclear transfer in mammals

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(page 312, citing the work of Hoppe, Illmensee, Kelly and McGrath). Further, in the description of nuclear transfer between species, the experiments proposed are general and focus on the analysis of affects on development of maternal factors and chromosomal factors (pages 301-302). First, with respect to claim 15, it is noted the nuclear material is obtained from a mammalian species, and that the particular example of a mammal nucleus fused to a xenopus oocyte would anticipate this claim. Second, Examiner would concede that Gurdon does not specifically make the embryos which meet the limitation of a mammalian oocyte and bovine oocyte recited in the method claims which result in the embryo of the instant claims, however, clearly Gurdon and contemplate and teach the general use of trans-species nuclear transfer for the study of development. Further, Gurdon specifically discusses the state of the art for mammalian nuclear transfer and provides an example wherein the nuclear material was from a mammal. In view of the teachings of the reference as whole, clearly the generation of other trans-species combinations, *i.e.* nuclear material of one species into a mammalian oocyte, for the study of development would be encompassed by the teachings of Gurdon.

Accordingly, Gurdun anticipates claims 12, 14 and 15, and therefore, the rejection is maintained.

Claims 12, 14 and 15 are newly rejected under 35 U.S.C. 102(e) as being anticipated by Stice *et al.* (WO 95/17500).

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In view of the claim amendments specifically directed towards generating a chimeric embryo, the amended claims are subject to a new rejection. It is noted that method claims 1 and 13, which are used to generate the product of claim 12 and 14, have been amended to recite new limitations to distinguish that the species used in the method are from different species. Claim 15 has been amended to recite that the first species must be a mammalian species. In the instant case, because the claimed embryo can encompass a single cell comprising the cytoplasm from one species and the nuclear material from a second different species, the claims now clearly encompass a chimeric single cell embryo. Stice *et al.* teach nuclear transfer procedures for producing non-human chimeric animals. Specifically, nuclear transfer techniques are used to introduce the nuclear material of one species of animal into the enucleated oocyte of a recipient animal (entire disclosure and specifically claimed in claims 1-39). Stice *et al.* teach that various combinations of species can be done and provide working examples where the oocyte is cultured for 16 hours, enucleated and donor nuclear material is transferred to the perivitelline space and fused by electrofusion (pages 35-44).

Accordingly, Stice *et al.* anticipates claims 12, 14 and 15.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

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such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-15 are newly rejected under 35 U.S.C. 103(a) as being unpatentable over Prather *et al.* (Biology of Reproduction, 1987, IDS reference), Gurdon (J. Cell. Sci. , 1986), Campbell *et al.* (WO 97/07668, March 1997, IDS reference), Telford *et al.* (Molecular Reproduction and Development, 1990, IDS reference), Dominko *et al.* (Molecular Reproduction and Development, 1997, IDS reference) in further view of Stice *et al.* (WO 95/17500)

As noted above in the 35 USC 102 rejection above, the methods encompassed by claims 1 and 13 have been amended to exclude intraspecies nuclear transfer and to specifically encompass interspecies nuclear transfer, necessitating a new grounds of rejection. In light of the claim amendments, an additional reference has been added to the basis of the previous rejection to more clearly set forth the generation of chimeric embryos using mammal, and more specifically bovine, recipient oocytes and/or nuclear material.

With respect to the previous rejection, Applicants summarize the teachings of the references noting that Prather *et al.* do not teach trans-species nuclear transfer, rather intraspecies transfer and Gurdon teaches nuclear transfer into an amphibian oocyte. Applicants note that a

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prima facie case of obviousness requires three criteria as set forth in MPEP 2142-2143 and citing *In re Vaeck* in support. Applicants argue that cited art does not teach nuclear transfer into an enucleated mammalian recipient oocyte from different species. Further, none of the secondary references cure the deficiencies of the primary references. Specifically, it is noted that the animals taught in Campbell *et al.* are generated by nuclear transfer, but not transpecies nuclear transfer. Dominko *et al.* teach methods of culturing embryos, but not embryos generated by nuclear transfer. In Telford *et al.*, it is pointed out that the limitation pointed to by Examiner in the basis of the rejection was interpreted incorrectly and does not provide evidence of the described embodiment. Citing *In re O'Farrell*, Applicants argue that the art does not suggest trans-species nuclear transfer into mammalian oocytes and provides no reasonable expectation of success, therefore a *prima facie* case for obviousness has not been established. See Applicants' amendment, pages 6-8. Applicants' arguments have been fully considered and not found persuasive as they apply to the instant rejection.

First, it is noted that the method claims have been amended to specifically exclude intraspecies nuclear transfer. However, it is noted above in the rejection made under 35 USC 102, Gurdon teach that transpecies nuclear transfer has been attempted for a wide variety of species of animals, and in view of the teachings of the reference as a whole provides for the use of recipient mammalian oocytes. Stice *et al.* has been added in response to Applicants amendment. Stice *et al.* clearly teach the generation of chimeric embryos, in particular for the generation of chimeric ungulates including bovine (for example claims 3, 4) and provides

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evidence that at the time of filing one of skill in the art was practicing nuclear transfer and using the methodology to generate chimeric embryos (see entire disclosure and in particular claim 32-37). Examiner agrees that Prather does not teach transpecies nuclear transfer, however it does provide guidance and evidence for the state of the art at the time of filing for nuclear transfer into bovine oocytes. Further, it is noted that the methodology for nuclear transfer and culturing of the resulting embryos taught in both Prather *et al.* and Stice *et al.* are very analogous, indicating that the conditions used by the artisan to generate and culture non-chimeric embryos would at least initially used for chimeric embryos. Each of Gurdon, Prather *et al.* and Stice *et al.* teach the nuclear transfer is possible using mammalian material, and Gurdon and Stice *et al.* clearly teach that transpecies nuclear transfer was practiced at the time of the claimed invention was made. Gurdon teaches that optimization of conditions would be necessary to produce a chimeric embryo capable of longer term culturing or capable of progressing through embryogenesis (Gurdon-pages 310-312). Applicants arguments that one of skill in the art would not use the culture conditions normal embryos for the culturing of chimeric embryos is unpersuasive. First, the culture conditions used in the generation of chimeric embryos in both Stice *et al.* and Gurdon are the same as is used for the culturing a normal non-chimeric embryo. Further, the instant disclosure also teaches to use conditions that are well known in the art for culturing an embryo (see page 19 and compare to Stice *et al.*). A review of the art of record does not indicate that conditions for culturing chimeric embryos would be different from those for culturing a normal embryo, though Gurdon does suggest that optimization may be necessary for increase embryo

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development. Clearly, as indicated in the specific teachings of Gurdon and Stice *et al.* and as disclosed in the instant specification, one of skill in the art would start with the culturing conditions for a normal embryos. Additionally, improvements in the culturing conditions for a particular species of oocyte and improvements in methodology for nuclear transfer will serve as a source of optimization of the general methodology disclosed in Gurdon and Stice *et al.*

As noted in the previous office action, Campbell *et al.* provides a recent status of nuclear transfer techniques, and in particular, Campbell teaches the use of donor cells which have been arrested in Go by various methods, maturation curves of the bovine oocyte, and activation of the NT unit by various techniques known in the art. Further, Campbell teaches that the described nuclear transfer technology can be used to generate transgenic animals as well (entire reference; summarized in abstract and specifically claimed). Additionally, Dominko *et al.* and Telford *et al.* both provide further guidance for the optimization of in using bovine oocytes. Specifically, Dominko *et al.* demonstrate that there is an increased efficiency in embryo development when the genetic material is transferred later than 8 hours of culturing (Figures 3 and 4). Examiner concedes that Telford *et al.* teach that there is a transition from maternal control (donor oocyte control) to the embryo for various species of animals and in particular, in the cow, this change occurs between 8-16 days. However, Stice *et al.* teaches that embryos that activation for most domestic animals will range from 16-52 hours (page 23; lines 16-27). In view of the work of Stice *et al.* and Dominko *et al.* it is clear that to establish the control of the genetic material

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transferred by nuclear transfer techniques, at least in the bovine, the artisan would deliver the nuclei after the 16 hour culture transition period.

Therefore, in view of the art as a whole, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to generate chimeric embryos by nuclear transfer techniques. As noted in Gurdon and Stice *et al.*, cross-species nuclear transfer has been performed for prior to the time of the claimed invention, however it was also observed that optimization of the methods wold be necessary. Campbell *et al.*, Telford *et al.* and Dominko *et al.* provide such optimization conditions detailing specific method steps and materials necessary to increase embryo development for the cow. One of skill in the art would have been motivated to use the teachings of Campbell *et al.*, Telford *et al.* and Dominko *et al.* because at the time of the claimed invention they represented the latest and best conditions/methods available to practice nuclear transfer techniques.

Thus, the claimed invention, as a whole, was clearly *prima facie* obvious in the absence of evidence to the contrary.

The art made of record and not relied upon is considered pertinent to Applicant's disclosure.

Dominko *et al.* Biology of Reproduction 60:1496-1502, is a post filing reference which includes some of instant inventors and provides further examples and evidence that chimeric

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embryos can be generated (page 1499; Table 1 and figure 2), though the development of the chimeric embryo does not result in a viable offspring (page 1500; table 2).

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (703)305-3732.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (703)305-4051.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist Pauline Farrier whose telephone number is (703)305-3550.

Papers related to this application may be submitted by facsimile transmission. Papers should be faxed via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center numbers are (703)308-4242 and (703)305-3014.

Deborah Crouch

Joseph T. Woitach

DEBORAH CROUCH
PRIMARY EXAMINER
GROUP 1630